UNITED STATES DISTRICT COURT 1 2 WESTERN DISTRICT OF WASHINGTON 3 AT SEATTLE 4 TERENCE FERNANDES, Derivatively On 5 Case No. 05-964 RSM Behalf of CELL THERAPEUTICS, INC., 6 VERIFIED AMENDED SHAREHOLDER Plaintiff, DERIVATIVE COMPLAINT FOR BREACH 7 OF FIDUCIARY DUTY, ABUSE OF VS. CONTROL, GROSS MISMANAGEMENT, 8 JAMES A. BIANCO, VARTAN WASTE OF CORPORATE ASSETS AND GREGORIAN, PHILLIP M NUDELMAN, UNJUST ENRICHMENT MARY O'NEIL MUNDINGER, JACK W. SINGER, and DOES 1-25, inclusive, 10 11 Defendants, 12 -and-13 CELL THERAPEUTICS, INC., a Washington 14 corporation, 15 Nominal Defendant. 16 DEMAND FOR JURY TRIAL 17 Plaintiff, by his attorneys, submits this Verified Amended Shareholder Derivative Complaint 18 (the "Complaint") against the defendants named herein. 19 NATURE OF THE ACTION 20 1. This is a shareholder derivative action brought by a shareholder of Cell Therapeutics, 21 Inc. ("Cell Therapeutics" or the "Company"), on behalf of the Company against certain of its officers 22 and directors seeking to remedy defendants' violations of state law, including breaches of fiduciary 23 duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment that 24 occurred between June 7, 2004 and the present (the "Relevant Period") and that have caused 25 substantial losses to Cell Therapeutics and other damages, such as to its reputation and goodwill. 26 VERIFIED AMENDED SHAREHOLDER MULFINGER LAW GROUP PLLC 13555 Bel-Red Road, Suite 111A DERIVATIVE COMPLAINT -1-

Bellevue, WA 98005 Telephone: 425/283-4155 • Facsimile: 425/283-4156 JURISDICTION AND VENUE

- 2. This Court has jurisdiction over all claims asserted herein pursuant to 28 U.S.C. \$1332(a)(2), because complete diversity exists between the plaintiff and each defendant, and the amount in controversy exceeds \$75,000. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.
- 3. This Court has supplemental jurisdiction pursuant to 28 U.S.C. §1367(a) over all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.
- 4. Venue is proper in the Court pursuant to 28 U.S.C. §1391(a) because one or more of the defendants either resides in or maintains executive offices in this District, a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein and aiding and abetting and conspiracy in violation of fiduciary duties owed to Cell Therapeutics occurred in this District, and defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

SUMMARY OF THE ACTION

5. Cell Therapeutics develops, acquires and commercializes treatments for cancer. The Company's research and in licensing activities are focused on identifying ways to treat cancer. The Company markets TRISENOX (arsenic trioxide) for the treatment of relapsed or refractory acute promyelocytic leukemia (APL) in the United States and in Europe. It is developing XYOTAX (paclitaxel poliglumex) for the potential treatment of non-small cell lung cancer (NSCLC) and ovarian cancer. The Company has completed enrollment of more than 1,700 patients in three pivotal Phase III trials of XYOTAX, known as STELLAR 2, 3 and 4, for the treatment of NSCLC. It also develops pixantrone, a compound in the class of drugs known as anthracyclines, for the potential treatment of non-Hodgkin's lymphoma (NHL) and has several clinical trials ongoing, including a pivotal Phase III trial for the potential treatment of relapsed aggressive NHL.

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- 7. In an effort to maintain their directorial and executive positions at the Company, defendants caused or allowed Cell Therapeutics to issue falsely positive statements regarding STELLAR 3's progress, which in turn artificially inflated the price of Cell Therapeutics common stock. This artificial inflation has exposed Cell Therapeutics to liability for violations of federal securities laws in connection with the sale of the Company's artificially inflated common stock in both a July 2004 secondary offering and a December 2004 private placement. These stock offerings were made while defendants were aware or should have been aware of adverse facts which suggested that major problems existed both in STELLAR 3's baseline assumptions and within its testing population. Despite these adverse facts, defendants caused or allowed the Company to falsely tout STELLAR 3's results as "encouraging."
- 8. On information and belief, plaintiff alleges that by November of 2003, when STELLAR 3 achieved full patient enrollment, patients were living on average far longer regardless of treatment than the study's assumed baseline four-month average for paclitaxel treatment in NSCLC PS2 patients. Importantly, this faulty assumption was based completely on data from two, small-scale studies that were never designed to determine the life expectancy of PS2 NSCLC patients undergoing paclitaxel therapy. As such, that both arms of the study were demonstrating

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survival data that was consistently longer than four months totally undermined any assertion that early data regarding a potential XYOTAX survivability benefit was "encouraging." In fact, this data suggested that the study's median survival assumption was fatally flawed.

- 9. On information and belief, plaintiff alleges that STELLAR 3 was being conducted primarily on Russian and Eastern European patients - a fact at odds with the Company's Relevant Period statements that STELLAR 3 was "mostly a U.S. and Western European study." In fact, the Company's statements emphasized the importance of the venue of such pivotal trials, explaining in regard to a competitor drug that its clinical research trial held outside the United States/Western Europe was likely to meet increased FDA scrutiny for approval, and that it was therefore inherently less reliable. Other Cell Therapeutics press releases commented on the Company's ongoing clinical trials for its ovarian cancer drug, the Company implored investors to "take some comfort in the fact that these important studies are being conducted in the U.S. and Europe." When the truth finally began to be revealed, the Company's shareholders learned for the first time that STELLAR 3 was conducted predominantly in Russia and Eastern Europe, and not in the United States or Western Europe as the Company's press releases had improperly disclosed.
- 10. Moreover, the patients enrolled in Russia and Eastern Europe were not as sick as patients enrolled elsewhere, and were on average ten years younger than patients enrolled in the United States and Western Europe. In fact, 18 patients from Russia and Eastern Europe were ultimately excluded from the results because their cancer had not yet progressed to the stage required to be eligible to participate in the study.
- 11. Finally, the Company's press releases improperly boasted that a significant percentage of patients enrolled in the study were able, on average, to tolerate four or more cycles of treatment, and that this fact was also "encouraging" because it suggested a survivability benefit over XYOTAX. These statements, however, were materially false and misleading because an increased tolerance to therapy suggested only that XYOTAX was less toxic than paclitaxel, a fact with little bearing on the question of overall survivability. Significantly, the Company's studies could not conclusively

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attribute the purportedly improved treatment tolerance to XYOTAX because a significant percentage of patients tolerating additional cycles of treatment were located in Eastern Europe and Russia, a population that was, less sick and on average ten years younger than patients located elsewhere. This younger and healthier group of patients was therefore able to tolerate more cycles of therapy than would older patients who fit squarely within STELLAR 3's eligibility criteria, regardless of treatment.

- 12. In the face of this litany of adverse facts regarding STELLAR 3's methodology and test population, the Company's statements that preliminary survivability data was "encouraging" were totally without basis. In turn, these misrepresentations caused an artificial inflation of the price of Cell Therapeutics common stock throughout the Relevant Period, which in turn exposed the Company to liability for violations of federal securities laws.
- 13. Finally, on March 7, 2005, the truth began to be revealed. On that day, the Company's shareholders were shocked when the Company announced that STELLAR 3 had missed its primary endpoint and failed to demonstrate a survivability benefit over paclitaxel. In direct reaction to this news, Cell Therapeutics lost more than 47 percent of its market capitalization or over \$428 million.
- 14. Five months later, in August 2005, four of the Company's directors, John M. Fluke ("Fluke"), Jr., Enrich Platzer ("Platzer"), Silvano Spinelli ("Spinelli") and Max E. Link ("Link") resigned from the Company. These directors resigned because they were unable to direct the Board of Directors (the "Board") to terminate those responsible for the wrongdoing alleged herein. Spinelli in his letter of resignation lamented, "My resignation is due to the denial by the Board of Directors of CTI to replace James Bianco, the Company's current Chief Executive Officer ("CEO"), with a more credible and reliable CEO in the interest of shareholders and the company." Accordingly, the remaining directors on the Board, who are also named as defendants herein, rather than act in the Company's and its shareholders' best interests, acted to protect themselves and the other defendants from liability.

THE PARTIES

- 15. Plaintiff Terence Fernandes is, and was at times relevant hereto, an owner and holder of Cell Therapeutics common stock. Plaintiff is a citizen of Georgia.
- 16. Nominal defendant Cell Therapeutics is a corporation organized and existing under the laws of the state of Washington with its headquarters located at 501 Elliott Avenue West, Suite 400, Seattle, Washington. Cell Therapeutics develops, acquires and commercializes treatments for cancer.
- 17. Defendant James A. Bianco ("Bianco") is, and at all times relevant hereto was principal founder, President, Chief Executive Officer ("CEO") and a director of Cell Therapeutics. Because of Bianco's positions, he knew the adverse non-public information about the business of Cell Therapeutics, specifically, that XYOTAX was not superior to the prevailing treatment, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Bianco participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and Securities and Exchange Commission ("SEC") filings. For FY:04 and FY:03, Cell Therapeutics paid defendant Bianco \$1,112,235 and \$3,053,665 in salary, bonus, restricted stock awards and other compensation, and granted him 125,000 options to purchase Cell Therapeutics stock in FY:03. Defendant Bianco is a citizen of Washington.
- 18. Defendant Jack W. Singer ("Singer") is, and at all times relevant hereto was, founder, Executive Vice President and Chief Medical Officer and a director of Cell Therapeutics. Because of Singer's positions, he knew the adverse non-public information about the business of Cell Therapeutics, specifically, that XYOTAX was not superior to the prevailing treatment, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance

at management and Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Singer participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. For FY:04 and FY:03, Cell Therapeutics paid defendant Singer \$560,887 and \$1,223,596 in salary, bonus, restricted stock awards and other compensation, and granted him 75,000 options to purchase Cell Therapeutics stock in FY:03. Defendant Singer is a citizen of Washington.

- 19. Defendant Vartan Gregorian ("Gregorian") is, and at all times relevant hereto was, a director of Cell Therapeutics. Because of Gregorian's position, he knew the adverse non-public information about the business of Cell Therapeutics, specifically, that XYOTAX was not superior to the prevailing treatment, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Gregorian participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Defendant Gregorian is a citizen of New York.
- 20. Defendant Phillip M. Nudelman ("Nudelman") is, and at all times relevant hereto was, a director of Cell Therapeutics. Because of Nudelman's position, he knew the adverse non-public information about the business of Cell Therapeutics, specifically, that XYOTAX was not superior to the prevailing treatment, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to him in connection therewith. During the Relevant Period, Nudelman participated in the issuance of false and/or misleading statements, including the

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preparation of the false and/or misleading press releases and SEC filings. Defendant Nudelman is a citizen Washington.

- 21. Defendant Mary O'Neil Mundinger ("Mundinger") is, and at all times relevant hereto was, a director of Cell Therapeutics. Because of Mundinger's position, she knew the adverse nonpublic information about the business of Cell Therapeutics, specifically, that XYOTAX was not superior to the prevailing treatment, as well as its finances, markets and present and future business prospects, via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at Board meetings and committees thereof and via reports and other information provided to her in connection therewith. During the Relevant Period, Mundinger participated in the issuance of false and/or misleading statements, including the preparation of the false and/or misleading press releases and SEC filings. Defendant Mundinger is a citizen of New York.
- 22. The defendants identified in ¶17-21 are referred to herein as the "Director Defendants." The defendants identified in ¶¶17-18 are referred to herein as the "Officer Defendants." Collectively, the Director Defendants and the Officer Defendants are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

23. By reason of their positions as officers, directors and/or fiduciaries of Cell Therapeutics and because of their ability to control the business and corporate affairs of Cell Therapeutics, the Individual Defendants owed Cell Therapeutics and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage Cell Therapeutics in a fair, just, honest and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Cell Therapeutics and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

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- 24. Each director and officer of the Company owes to Cell Therapeutics and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company's flagship drug XYOTAX, as well as the Company's forecasts so that the market price of the Company's stock would be based on truthful and accurate information.
- 25. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Cell Therapeutics, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with Cell Therapeutics, each of the Individual Defendants had access to adverse non public information about the true risks of clinical study failure and prospects for failure to gain marketing approval for XYOTAX due to the corneal clearing primary endpoint required by the FDA, as well as the Company's financial prospects.
- 26. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Cell Therapeutics, and was at all times acting within the course and scope of such agency.
- 27. To discharge their duties, the officers and directors of Cell Therapeutics were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Cell Therapeutics were required to, among other things:
- (a) refrain from acting upon material inside corporate information to benefit themselves;

- (b) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the FDA, SEC and the investing public;
- (c) conduct the affairs of the Company in an efficient, business like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (d) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's product and financial prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's public statements would be true and accurate at all times;
- (e) remain informed as to how Cell Therapeutics conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and
- (f) ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.
- 28. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Cell Therapeutics, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and/or directors of the Company

during the Relevant Period has been ratified by the remaining Individual Defendants who

collectively comprised all of Cell Therapeutics' Board during the Relevant Period.

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29. The Individual Defendants breached their duties of loyalty and good faith by allowing defendants to cause or by themselves causing the Company to fail to disclose the true risks of clinical study failure and prospects for failure to gain marketing approval for XYOTAX due to the corneal clearing primary endpoint required by the FDA and to misrepresent its financial prospects, as detailed herein *infra*, and by failing to prevent the Individual Defendants from taking such illegal actions. In addition, as a result of defendants' illegal actions and course of conduct during the

Relevant Period, the Company is now the subject of several class action lawsuits that allege

violations of federal securities laws. As a result, Cell Therapeutics has expended and will continue

to expend significant sums of money. Such expenditures include, but are not limited to:

- costs incurred to carry out internal investigations, including legal fees paid to (a) outside counsel; and
- (b) costs incurred in investigating and defending Cell Therapeutics and certain officers in the class actions, plus potentially millions of dollars in settlements or to satisfy an adverse judgment.
- 30. Moreover, these actions have irreparably damaged Cell Therapeutics' corporate image and goodwill. For at least the foreseeable future, Cell Therapeutics will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Cell Therapeutics' ability to raise equity capital or debt on favorable terms in the future is now impaired.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

31. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the

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wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breach of their respective duties.

- 32. During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to and did: (i) conceal the fact that the Company was issuing false and misleading statement about the true risks of clinical study failure and prospects for failure to gain marketing approval for XYOTAX; (ii) maintain the Individual Defendants' executive and directorial positions at Cell Therapeutics and the profits, power and prestige that the Individual Defendants enjoyed as a result of these positions; and (iii) deceive the investing public, including shareholders of Cell Therapeutics, regarding the Individual Defendants' management of Cell Therapeutics' operations and the Company's future business prospects. In furtherance of this plan, conspiracy and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.
- 33. The Individual Defendants engaged in a conspiracy, common enterprise and/or common course of conduct commencing by at least June 2004 and continuing thereafter. During this time the Individual Defendants caused the Company to conceal the true fact that XYOTAX was not superior to the prevailing treatment. In addition, defendants also made other specific, false statements about Cell Therapeutics' future business prospects, as alleged herein.
- 34. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment; to conceal adverse information concerning the Company's future business prospects; and to artificially inflate the price of Cell Therapeutics common stock so they could: (i) protect and enhance their executive and directorial positions and the substantial compensation and prestige they obtained as a result thereof.
- 35. The Individual Defendants accomplished their conspiracy, common enterprise and/or common course of conduct by causing the Company to purposefully, recklessly or negligently issue

false and misleading press releases about the prolonged survival and relative low adverse event rates being observed in XYOTAX pivotal trial in non-small cell lung cancer, as well as its financial prospects. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary and substantial participant in the conspiracy, common enterprise and/or common course of conduct complained of herein.

36. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

SUBSTANTIVE ALLEGATIONS

- 37. Cell Therapeutics was formed in 1991 and incorporated in the State of Washington. The Company develops, acquires and commercializes treatments for cancer. In June 1998, the Company acquired an exclusive worldwide license from PG-TXL Company ("PG-TXL") to the rights for paclitaxel poliglumex and all potential uses of PG-TXL's polymer technology. Paclitaxel poliglumex is paclitaxel linked to a polyglutamate polymer and is branded by Cell Therapeutics as XYOTAX.
- 38. Before, during, and throughout the Relevant Period, Cell Therapeutics incurred operating losses. Between FY:00 and FY:04, Cell Therapeutics incurred increasingly larger operating losses of \$55,902,000, \$83,485,000, \$98,787,000, \$122,585,000 and \$240,828,000, respectively. These losses from operations each year were attributed chiefly to the increased operating expenses the Company faced. For FY:00 through FY:04, Cell Therapeutics incurred increasingly higher operating expenses of \$56,404,000, \$89,721,000, \$115,683,000, \$147,350,000 and \$270,422,000, respectively. Most of these operating expenses stemmed directly from Cell Therapeutics' three major Phase III trials of XYOTAX. Specifically, R&D expenses for the

XYOTAX trials alone were \$18,345,000, \$26,193,000, \$52,888,000 and \$41,638,000 during FY:01 through FY:04.

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The Development of XYOTAX

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39. In June 2003, the Individual Defendants caused or allowed the Company to conduct a private placement offering of convertible, senior subordinated notes that allowed the Company to raise \$75 million to offset its losses. Just a few months later, beginning in October 2003, the Individual Defendants directed Cell Therapeutics to undertake a company-wide restructuring plan which resulted in layoffs of a large number of employees and occurred in two stages: the first in October 2003 and the second in November or December 2003. The purpose of the restructuring was to siphon more money to the Company's ongoing clinical trials.

40. Little more than one year later, the Individual Defendants caused or allowed Cell Therapeutics to seek additional financing through a secondary offering. On July 14, 2004, pursuant to a shelf registration filed in February 2004, the Company announced the offering of eight million shares, at a price of \$4.75 per share. Two weeks later, on July 28, 2004, the Individual Defendants caused or allowed Cell Therapeutics to increase its offering to nine million shares, giving underwriters the option of purchasing an additional 1.35 million shares. Underwriters exercised their option to purchase the additional 1.35 million shares, and Cell Therapeutics' total offering of 10.35 million shares raised gross proceeds of \$49.2 million in August 2004, according to the Company's Form 10-Q for the third quarter, ended September 30, 2004.

41. On December 20, 2004, the Individual Defendants caused or allowed the Company to complete another private placement of 2.3 million shares of Cell Therapeutics' common stock, for proceeds of \$18 million.

the front-line - *i.e.*, initial chemotherapy treatment - of PS2 patients with NSCLC. XYOTAX treats

cancer by stopping cell division in order to inhibit cell growth and uses a biodegradable protein

polymer to deliver the chemotherapy paclitaxel more selectively to tumor tissue than paclitaxel

Throughout the Relevant Period, Cell Therapeutics developed XYOTAX to address

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alone. The Individual Defendants caused or allowed the Company to issue public statements that indicated that XYOTAX's ability to deliver targeted chemotherapy treatment was the key to XYOTAX's purported survivability benefit over paclitaxel.

- 43. According to the American Cancer Society, approximately 146,000 new cases of NSCLC will be diagnosed in the United States in 2005, with approximately 128,000 of these patients expected to receive chemotherapy. Of the estimated 128,000 NSCLC patients who receive chemotherapy, only approximately 32,000 are classified as PS2.
- 44. In general, PS2 patients are partially ambulatory and capable of self-care, but are unable to carry out normal work activities. During Cell Therapeutics' February 28, 2005 conference call with analysts and investors, defendant Bianco explained the difference between PSO, PS1 and PS2 patients. Bianco stated that a "PSO should be asymptomatic, PS1s should be symptomatic with normal fully ambulatory [functions, and] PS2[s] will not be fully ambulatory." Additionally, PS2 patients were described in a December 22, 2003 Cell Therapeutics press release as those "whose disease has progressed to the point where they are unable to work and unable to get out of bed up to 50% of the time."
- 45. Prior to the start of the Relevant Period, Taxol was one of only two marketed drugs approved by the FDA for the treatment of NSCLC. Taxol is considered the "standard of care" for NSCLC.
- 46. On March 4, 2005, the Individual Defendants caused or allowed the Company to file its FY:04 Form 10-K with the SEC. The filing stated that XYOTAX "may have ... superior antitumor activity than marketed taxanes," such as Taxol. In addition, the filing indicated that XYOTAX offered "less severe side effects, including a reduction in severe neutropenia, allergic reactions and hair loss." Because Taxol is a formulation of paclitaxel in a mixture of polyethoxylated castor oil and ethanol, it is extremely irritating to blood vessels and requires surgical placement of a large catheter for administration, according to the FY:04 Form 10-K. In addition, Taxol can cause severe life threatening allergic reactions and typically requires a minimum of three hours of

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intravenous infusion, and transportation of patients to and from their treatment location. In contrast, according to the FY:04 Form 10-K, XYOTAX is approximately 80,000 times more water-soluble than paclitaxel alone, allowing it to be dissolved in a simple water and sugar based solution and infused in the patient for approximately ten minutes. In addition, XYOTAX does not require routine pre-medication with steroids and antihistamines to prevent severe allergic reactions and patients can drive themselves to and from treatment centers. Finally, the filing stated, based on the drug's performance in Phase II trials, that XYOTAX would allow delivery of higher, better tolerated, cumulative doses than could be achieved with paclitaxel.

47. Before the Phase III XYOTAX trials, clinical data on PS2 patients with NSCLC was scarce because, historically, they had been excluded from cancer treatment studies, or grouped as "special populations" of larger studies that focused on PSO or PS1 patients. Indeed, according to Dr. Corey Langer ("Dr. Langer") at a Cell Therapeutics sponsored presentation on November 3, 2004, most clinical data that existed concerning PS2 patients came from Phase II trials. During the November 3, 2004 presentation, Dr. Langer further indicated that if and when PS2 patients were studied, they were not treated under the same protocols as PSO or PS 1. For example, the Schiller and Lilenbaum studies each tested marginal sample sizes of PS2 patients to examine the effect of Taxol on PS2 patients. However, neither study directly addressed life expectancy of PS2s undergoing paclitaxel/carboplatin therapy (the control arm of STELLAR 3). The Schiller study was a randomized study conducted by Dr. Joan H. Schiller for the Eastern Cooperative Oncology Group, and published by the New England Journal of Medicine, comparing four chemotherapy regimens to determine whether any of three chemotherapy regimens was superior to cisplatin and paclitaxel in patients with advanced NSCLC. See Joan H. Schiller, M.D., et al., Comparison of Four Chemotherapy Regimens for Advanced Non-Small-Cell Lung Cancer, 346 N. Engl. J. Med. 2002. The Lilenbaum study was 2 randomized Phase III trial of carboplatin and paclitaxel v. paclitaxel alone in patients with Stage IIIB and Stage IV NSCLC, conducted by Rogerio C. Lilenbaum for the

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American Society of Clinical Oncology ("ASCO"), comparing survival, quality of life and costeffectiveness in PSO and PS 1 patients, with a subgroup analysis of elderly and PS2 patients.

- 48. Indeed, during Cell Therapeutics' October 24, 2002 conference call, defendant Bianco boasted that, "[STELLAR 3] is the only randomized PS2 Phase III trial that we are aware of," to study PS2 patients exclusively, and on a large-scale, and therefore could be a "landmark" trial in the disease. Similarly, while presenting the final results for STELLAR 3 at the 2005 ASCO Conference, defendants touted the study as the "first dedicated Phase III trial ever conducted in [chemotherapy] treatment-naive PS2 patients with non-small cell lung cancer." As a result of the dearth of scholarly research on the NSCLC PS2 population, precisely how long such patients could be expected to live under a paclitaxel treatment regimen remained unclear.
- 49. According to the FY:04 Form 10-K, PS2 patients generally have a significantly shorter median survival rate than healthier patients. Under the limited clinical data available, PS2 patients demonstrate a median survival rate of approximately four months with paclitaxel. For example, according to the FY:04 Form 10-K, data from a randomized trial of paclitaxel in NSCLC patients showed a median survival rate of approximately 2.4 months in front-line therapy of PS2 patients when administered as a single-agent and 4.7 months when administered in combination with platinum-containing chemotherapy (such as carboplatin). Similarly, Taxol yielded median survival rates of 3.9 and 4.7 months, respectively, in the Schiller and Lilenbaum studies, according to a Cell Therapeutics conference call that was conducted on November 11, 2004 with analysts. The Schiller and Lilenbaum studies also indicated that PS2 patients generally tolerated only 2 cycles of chemotherapy treatment, with an average of only 21 percent of PS2 patients tolerating 4 or more cycles of treatment, according to the February 28, 2005 conference call. Although neither of these studies directly addressed expected life expectancy of PS2 patients undergoing paclitaxel/carboplatin therapy (the control arm of the Stellar 3 trial), Cell Therapeutics utilized the four-month average rate of survival as a baseline comparison in setting survivability assumptions for STELLAR 3.

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50. Plaintiff alleges on information and belief that there was hardly any data for the control group of approved drugs before STELLAR 3, and therefore, there was little basis upon which to make any accurate prediction regarding the anticipated survival rate of PS2 patients. As a result, the Company's clinical department did not feel comfortable with the design of the STELLAR 3 trial in this regard.

The STELLAR 3 Trial

- 51. In October 2002, the Company announced that it had received approval from the FDA to proceed with two Phase III trials of XYOTAX for the front-line treatment of PS2 patients with NSCLC. The trials, named STELLAR 3 and STELLAR 4, evaluated whether XYOTAX increases the overall survival rate in PS2 NSCLC patients when compared to paclitaxel. In October 2002, the Company also received FDA approval to proceed with one Phase III trial of XYOTAX for the second-line treatment of NSCLC, known as STELLAR 2.
- .mg/m2 in combination with carboplatin versus standard paclitaxel (Taxol) at 225 mg/m2 and carboplatin. The study was designed to include patients stratified by stage of cancer, gender, history of nervous system metastasis (*i.e.*, the spread of the cancer), and geographic origin. But only those patients whose cancer had progressed to Stage IIIB, Stage IV, or who had recurrent NSCLC were eligible to participate. In NSCLC, Stage IIIB cancer means one of four things: (i) there is cancer spread to nodes on the other side of the chest (from where the cancer originated) or to nodes above either collarbone; (ii) there is more than one tumor in the affected lobe of the lung; (iii) the tumor has grown into another major structure of the chest, *i.e.*, the heart, windpipe, gullet, or a major blood vessel; or (iv) there is a fluid collection around the lung that contains cancer cells. Stage IV lung cancer means that the cancer has spread to another lobe of the lung from where it started or to another part of the body, *i.e.*, the liver or bones. The primary endpoint of STELLAR 3 was survival with a targeted goal of a 37% increased median survival from a historic baseline of 4 months on the control arm to a targeted median survival of 5.5 months on the XYOTAX arm.

- 53. Because defendants set survivability as STELLAR 3's primary endpoint, the FDA approved "fast track" designation for the trial. "Fast track" designation means the FDA will facilitate and expedite the development and review of a new drug application ("NDA") for the approval of a new drug if it is intended for the treatment of a serious or life-threatening condition, demonstrates the potential to address an "unmet medical need," or demonstrates the potential to provide a meaningful benefit over existing treatments. An expedited review as defined by the FDA generally provides for a review within six months of the Company's submission of an NDA.
- 54. Thus, as the Individual Defendants knew or should have known, survivability was highly likely to be the only showing that would win FDA approval. In fact, according to a statement by Cell Therapeutics' Chief Medical Officer during an April 24, 2002 earnings conference call, the FDA mandated survivability as the primary endpoint for the STELLAR 3 trial.
- 55. Thus, STELLAR 3 was designed as a randomized Phase III trial that compared the overall survival effectiveness of XYOTAX/paclitaxel plus carboplatin to that of paclitaxel plus carboplatin in treating patients who have Stage IIIB, Stage IV or recurrent NSCLC. STELLAR 3 was designed as a "blinded" study, meaning that the participants and/or the sponsor are unaware of whether they are in the experimental or control arm of the study. In one arm of the STELLAR 3 trial, patients received an intravenous infusion of XYOTAX/paclitaxel over ten minutes and an intravenous infusion of carboplatin over 30 minutes. In the second arm, patients received an intravenous infusion of paclitaxel over three hours and an intravenous infusion of carboplatin over 30 minutes. The study was designed to enroll a total of 370 patients (although 400 were actually enrolled), and treatments were repeated in both arms every 21 days for a maximum of six possible treatments. Patients were followed at three weeks out, and then every eight weeks thereafter. The study was to conclude when 311 deaths or "events" were reached. The study was fully enrolled on November 25, 2003. The Company announced that STELLAR 3 reached 311 "events" on January 27, 2005.

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1 56. On October 24, 2002, during the Company's quarterly earnings conference call with 2 analysts and investors, defendant Bianco announced that enrollment in STELLAR 3 would begin in 3 mid to late November 2002. During the conference call, Bianco also informed investors that, of the 70 to 100 test locations world-wide, "a majority of [the] patients [enrolled would] originat[e] here 4 5 in the United States." These pronouncements indicated that STELLAR 3 would be predominantly conducted in the United States and Western Europe, and at no time prior to the end of the Relevant 6 7 Period did the Individual Defendants insure that the Company correct these statements by disclosing 8 that a large number of trials were conducted in Eastern Europe. Further, the Individual Defendants caused or allowed the Company to tout the benefits of conducting clinical trials in the United States 10 or Western Europe. For example, during an April 24, 2002 conference call, certain of the defendants 11 stated that the geographic location of XYOTAX drug trials for ovarian cancer, which were being 12 conducted by the GYN/Oncology Group, would bolster the credibility of these trials in the eyes of 13 the FDA. Specifically, during the conference call, defendant Bianco stated, "you should take some 14 comfort in the fact that these important studies are being conducted in the U.S. and [Western] 15 Europe."

57. Studies conducted outside the United States or Western Europe are inferior because they lack quality control and reliability, and using such studies can create more difficulty in obtaining FDA approval. For example, the FDA's resistance to broadly accepting clinical data from places such as Eastern Europe and Russia is demonstrated by the administration's adoption of International Conference on Harmonization of Technical Requirements for the Regulation of Pharmaceuticals for Human Use ("ICH") guidelines. ICH 5, for example, provides guidance for the consideration of ethnic factors in the acceptability of foreign clinical data and identifies problems encountered in extrapolating foreign data (such as genetics, diet, standard medical care and practices, and the stringency of how clinical trials are run) to the population of the region in which the NDA will be approved.

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- 58. During the April 24, 2002 conference call, defendant Bianco dismissed data from a competitor's study being conducted in India because results from studies outside Western Europe or the United States would experience difficulty complying with FDA requirements. Specifically, Bianco stated that he was "uncertain" about a phase three metastatic breast cancer study that was then underway because "abstract data in the ACSO book of phase two trials [sic] looked like the majority of that data was being conducted in territories that would have difficulty vis-a-vie the FDA's acceptance of the data."
- 59. During the STELLAR 3 trial, Cell Therapeutics hired a North Carolina-based firm, Pharmaceutical Product Development, Inc. ("PPD"). PPD was responsible for ensuring that the STELLAR 3 protocol was followed properly.
- 60. PPD was also responsible for distributing to and collecting from each site case report forms, upon which each site investigator records all pertinent individual patient data. Additionally, case report forms contain information describing a patient's "physical characteristics" including age, race and gender, as well as medical information including blood pressure and blood analysis results, to determine whether a patient should be included in the study. Case report forms also contain a Demographic Form, which lists information like the patient's age, race and sex, while the History Form lists information about the patient's medical history. In a lung cancer drug study the History Form would also include the results of X-Rays, CAT-Scans and blood tests. Additionally, a case report form would typically contain information describing a patient's stage of disease, performance status, site location of treatment, and an extensive checklist of various health-related symptoms which typically includes a checkbox for identifying those patients that are not formally eligible for the study, but enrolled in it for some other reason and why.
- 61. Trial specific information such as what days and times Drug A or Drug B was administered, infusion times, side effects and other information regarding how the patient is responding to the drug is recorded on the case report form. Drug dosage information, drug lot

number, concomitant medications and adverse experiences are also typically recorded on a case report form.

- 62. Indeed, the only information that was "blinded" to Cell Therapeutics and PPD from the STELLAR 3 case report forms was the treatment information, *i.e.*, whether the patient received XYOTAX or control. In cancer drug trials, however, it is nearly impossible to effectively "blind" the sponsor or participants from knowing which drug is being administered to whom. Infusion times and frequencies are factors that can tip off what drug various patients were receiving. Oncology trials are widely considered to be difficult or impossible to blind.
- 63. Moreover, FDA regulations require, among other things, that all pertinent information be properly recorded and updated on the case report forms throughout an investigational drug study. For example, section 312.57 of the Federal Register requires the Company to maintain all written records of any disposition of the drug during the trial. Similarly, Cell Therapeutics was required to know the location of every test site during the trial because, in accordance with section 312.59, the sponsor must account for the use and/or return of all supplies of the investigational drug. Indeed, the FDA has established a Bioresearch Monitoring Program to ensure that investigational drug studies comply with these FDA regulations, and that all pertinent patient data relating to the study is properly documented in the subject's CRF. A study may be suspended or terminated for failure to comply with these, or other regulations.
- 64. On information and belief, plaintiff alleges that throughout the trial, PPD routinely collected cause report forms from each test site and entered the data into a database. PPD continuously monitored STELLAR 3's database and provided updates to the Company so that its internal database could track the PPD's database in parallel with approximately a one-week delay in receiving the most current data. In addition, the XYOTAX Project Team, comprised of the Company's Medical Director and Project Manager, and the Project Manager at PPD, received this pooled data during the STELLAR 3 trial.

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On information and belief plaintiff alleges that defendant Bianco reviewed the case report forms for STELLAR 3. Indeed, Bianco's access to, and review of, the STELLAR 3 case report forms allowed him and the other defendants to know virtually everything about the progress of the trial. Further, federal regulations required that Cell Therapeutics establish a Data Safety Monitoring Board to conduct audits and provide data to the Company concerning patient safety during the STELLAR 3 trial.

By virtue of their access to data contained in Cell Therapeutics' internal database and 66. review of case report forms and Data Safety Monitoring Board audits during the Relevant Period, the Individual Defendants knew or should have known, by at least November 25, 2003, when STELLAR 3's full enrollment was completed: (i) the geographic location of each test site; (ii) where each patient enrolled in the study was being treated (i.e., how many patients were being treated at each test site); (iii) whether a patient had Stage IIIB or Stage IV cancer, or whether an enrolled patient was actually ineligible because their cancer had not progressed that far; (iv) whether a patient was truly PS2 status or ineligible because their symptoms were still asymptomatic; (v) the age of each enrolled patient; and (vi) which drug each patient was receiving.

STELLAR 3 Was Not a Blinded Study

- 67. Because of STELLAR 3's design, defendants were supposedly "blinded" from knowing whether a patient was enrolled in the XYOTAX or the paclitaxel arm of the study. In fact, the opposite was true. This is significant because, during the Relevant Period, the Individual Defendants caused or allowed Cell Therapeutics to tout the fact that the Company was seeing an increased median one-year survival rate in PS2 patients enrolled in STELLAR 3, and that this result was "encouraging" news to investors that XYOTAX would meet its primary endpoint of a survivability benefit over paclitaxel.
- 68. On June 7, 2004, the Individual Defendants caused Cell Therapeutics to issue a press release in which it stated that there were "encouraging developments in the STELLAR 3 pivotal trial." On December 16, 2004, the Individual Defendants caused or allowed Cell Therapeutics to

issue another press release touting similarly "encouraging findings from STELLAR 3. The Individual Defendants stated that "the increase in ... the survival estimates are very encouraging." Then again, on January 27, 2005, the Individual Defendants caused or allowed the Company to issue a press release again touting that, "The median and one-year survival estimates in STELLAR 3 are very encouraging." Additionally, during a February 28, 2005 conference call, defendant Bianco indicated that the patients enrolled in the trial were "acutely sick with their lung cancer and that's probably more likely the case outside the U.S. than inside the U.S."

69. In fact, the improved survival rate over the control was not the result of XYOTAX's efficacy, but rather a myriad of other factors of which the Individual Defendants knew or should have known, including: (i) STELLAR 3 was predominantly enrolled in Eastern Europe and Russia, testing locations that Cell Therapeutics strongly implied would produce less reliable data, in complete contradiction to the Company's statements that the trial was being held in Western Europe and the United States; (ii) the Eastern European and Russian patients were, on average, ten years younger than patients from the United States, Western Europe and Canada; (iii) the Eastern European and Russian patients were also not as sick as patients located elsewhere (18 patients were later excluded because they were Stage IIIA); and (iv) patients were living far longer, on average, than the four month baseline assumption set by Cell Therapeutics, regardless of which drug was being administered, indicating that the median survival assumption was critically flawed. The Company's statements in the face of these known facts rendered them materially false and misleading.

70. On information and belief, plaintiff alleges that the nature of the two test drugs and how they were administered left no doubt either for the patient or the doctor, as to which patients were receiving the test drug and which were receiving the control drug. Patients knew what drug they're getting and the physicians know what drug they're giving because one is a ten-minute infusion versus a three-hour infusion.

allowed them to "unblind" data for the STELLAR 3 trial. First, since Cell Therapeutics was the

sponsor of STELLAR 3, the Individual Defendants had access to detailed information regarding both

report forms for STELLAR 3, the Individual Defendants could easily determine which drug each

patient was receiving from notations recording the markedly different infusion times for the two

treatments. Finally, in order to ensure compliance with FDA regulations, the Officer Defendants

monitored the STELLAR 3 database during the Relevant Period to review updated information

the case report forms, such as site locations, patient enrollment per site and progression of illness.

For example, during a Cell Therapeutics' November 9, 2004 conference call with analysts, defendant

Bianco implied that he knew where each test site was located when he stated that the Company's

internal clinical group had been calling individual test sites to confirm "event" occurrences.

Additionally, because defendant Bianco reviewed the case report forms, he knew at which test site

each patient was being treated. Moreover, during the November 9, 2004 conference call, defendant

Bianco indicated that the Company had conducted audits of each test site to confirm patient

("Burchenal") of Lehman Brothers questioned defendant Bianco regarding the "blindedness" of the

STELLAR 3 study. Specifically, James Burchenal stated, "Obviously we are able to see who gets a

10-minute infusion versus using a three-hour infusion," and then asked, "do you have the breakdown

and do you know what the median survival is for those two groups?" The exchange continued as

During the Relevant Period, the Individual Defendants had access to information that

Defendant Bianco also publicly confirmed his knowledge of patient data contained in

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contained in the case report forms.

XYOTAX and paclitaxel, and the distinguishing features of each drug. Second, by reviewing case 4 5

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follows:

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Defendant Bianco: I would be unblinding the study.

James Berchenal:

eligibility based on cancer stage and performance status.

Well, it's essentially open label, right?

Indeed, during the November 9, 2004 conference call, analyst James Burchenal

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Defendant Bianco: That's unblinding the study.

In fact, as Burchenal's exasperated question suggested, the Individual Defendants had access to the breakdown and median survival rates for each group because of the case report files and the STELLAR 3 database.

74. Accordingly, the Individual Defendants had access to information that suggested that patients in Eastern Europe and Russia, in both arms of the study, were living far longer than anticipated. Indeed, on average, patients in both arms of the trial outlived not only the baseline comparison four-month median survival rate for PS2 patients, but also the longer 5.5 month target goal for the study. These anomalies suggest that there were serious problems both with STELLAR 3's methodology, as well as with the characteristics of its test population.

IMPROPER STATEMENTS

75. The Individual Defendants by their fiduciary duties of care, good faith and loyalty owed to Cell Therapeutics a duty to insure that the Company's public statements fairly presented, in all material respects, material information concerning the development of XYOTAX, which is one of the most important aspects of Cell Therapeutics' business, as well as all other issues material to the Company's operations. In order to adequately carry out these duties, it is necessary for the Individual Defendants to know and understand the material non-public information to be either disclosed or omitted from the Company's public statements. Defendants Bianco and Singer as officers of Cell Therapeutics, had ample opportunity to discuss this material information with their fellow officers at management meetings and via internal corporate documents and reports. Moreover, defendants Bianco, Singer, Gregorian, Nudelman and Mundinger as directors of Cell Therapeutics had ample opportunity to discuss this material information with management and fellow directors at any of the Board meetings that occurred during the Relevant Period as well as at meetings of Committees of the Board. Despite these duties, the Individual Defendants negligently, recklessly, and/or intentionally caused or allowed, by their actions or inactions, the following

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improper statements to be disseminated by Cell Therapeutics to the investing public and the Company's shareholders during the Relevant Period.

On June 7, 2004, the Individual Defendants caused or allowed Cell Therapeutics to issue a press release entitled "Prolonged Median and One-Year Survival Rate Estimate in XYOTAXTM Pivotal Lung Cancer Study Extends Data Release to Early 2005." The press release

At a conference sponsored by Cell Therapeutics, Inc. (CTI) during the 40th Annual Meeting of the American Society of Clinical Oncology, five cancer experts provided a clinical perspective on the continuing investigation of XYOTAX, pixantrone and TRISENOX (arsenic trioxide). In an update on the status of the phase III trials in non-small cell lung cancer, Philip Bonomi, M.D. of Rush-Presbyterian-St. Luke's Medical Center presented encouraging developments in the STELLAR 3 pivotal trial. As a result of higher than historically predicted survival rates the projected number of events required to perform the primary efficacy analysis and data release of the STELLAR 3 trial will not occur until early 2005.

"The STELLAR 3 and 4 studies are the largest studies ever conducted in poor performance status (PS2) patients. I am impressed with the median number of cycles of doublet therapy administered in STELLAR 3, particularly in light of recently published results from studies of the standard paclitaxel and carboplatin combination therapy. The number of cycles of therapy is unusual for a PS2 patient population and may reflect improved tolerability of XYOTAX," commented Bonomi. "The median survival estimate is longer than data from other trials presented at this year's ASCO

Director of Oncology at University of Mississippi and the chair of the GOG ovarian committee, Tate Thigpen, M.D. provided an overview of the GOG phase I/II experience with XYOTAX in more than 200 patients, along with an update on the phase III pivotal trial in the maintenance treatment of ovarian cancer, noting the GOG expects to file its Special Protocol Assessment (SPA) with the FDA shortly. This is the first time the GOG will have filed an SPA with the FDA for the maintenance treatment of patients in remission with ovarian cancer.

"Based on our phase I/II experience with XYOTAX and the data suggesting that maintenance taxane therapy improves overall survival, we believe we have designed a trial that has every chance of success. This will be the largest trial ever conducted in the maintenance treatment of ovarian cancer. The trial is designed to ensure that we can show a clinically meaningful difference in survival," noted Thigpen. "As an organization, the GOG has been at the forefront of ovarian cancer treatment and research and we are looking forward to initiating this trial with the hope of offering ovarian cancer patients a new, less toxic, more effective treatment."

77. On July 27, 2004, the Individual Defendants caused or allowed Cell Therapeutics to issue a press release entitled "Cell Therapeutics, Inc. Posts Highest TRISENOX® Sales Revenues

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Since Product Launch; Second Quarter Sales Rise More Than 100% Over First Quarter Sales and 2 50% Over Same Period in 2003." The press release stated in part: 3 Cell Therapeutics, Inc. (CTI) reported financial results for the second quarter ended June 30, 2004. Total revenues for the quarter were \$8.3 million compared to \$6.1 million in the second quarter of 2003. Net product sales for TRISENOX® (arsenic 4 trioxide) were \$7.9 million compared to \$5.3 million for the same period in 2003. 5 CTI reported a net loss for the quarter of \$37.5 million (\$0.75 per share) compared to a net loss of \$30.8 million (\$0.93 per share) for the same period in 2003. 6 The Company ended the quarter with approximately \$90 million in cash, cash 7 equivalents, securities available-for-sale, and interest receivable. 8 "We're encouraged by the rebound in TRISENOX® sales, making this the best quarter since launch," stated James A. Bianco, M.D., President and CEO of CTI. 9 "We are also very excited about the completion of enrollment in our XYOTAXTM STELLAR lung cancer trials. Our STELLAR 3 data release has been pushed out to early 2005 due to longer patient survival estimates. As such our efforts are now 10 focused on pre-launch activities and being in position to submit a new drug application as soon as possible following positive trial results." 11 12 78. On July 28, 2004, the Individual Defendants caused or allowed Cell Therapeutics to 13 issue a press release entitled "Cell Therapeutics, Inc. Announces Pricing of Upsized Public Offering of 9.000,000 Shares of Common Stock." The press release stated in part: 14 15 Cell Therapeutics, Inc. (CTI) today announced the pricing of the underwritten public offering of 9,000,000 shares of its common stock at a public offering price of \$4.75 16 per share. 17 These shares were sold under an existing shelf registration statement. The offering was increased by 1,000,000 shares over the proposed offering announced on 18 July 14, 2004. In connection with this offering, CTI has granted the underwriters an option to purchase up to 1,350,000 additional shares to cover over-allotments. All 19 shares are being sold by CTI. 20 79. On August 31, 2004, the Individual Defendants caused or allowed Cell Therapeutics 21 to announce that the underwriters of its recent 9,000,000 share common stock public offering had 22 exercised their over-allotment option and "purchased 1,350,000 additional shares of common stock 23 from CTI at a price of \$4.75 per share minus the underwriting discounts. CTI sold a total of 24 10,350,000 shares of common stock in the offering, including the shares covered by the exercised 25 over-allotment option, for aggregate gross proceeds of approximately \$49.16 million."

1	80. On November 9, 2004, the Individual Defendants caused or allowed Cell
2	Therapeutics to issue a press release entitled "Trisenox® Sales Increase 42 Percent Over Same
3	Period in 2003; Pivotal Trial Data for XYOTAX TM on Schedule for Release in Early 2005." The
4	press release stated in part:
5	Cell Therapeutics, Inc. (CTI) reported financial results for the third quarter ended
6	September 30, 2004. Total revenues for the quarter were \$8.7 million compared to \$6.5 million in the third quarter of 2003. Net product sales for TRISENOX(R)
7	(arsenic trioxide) rose to \$8.4 million compared to \$5.9 million for the same period in 2003.
8	CTI reported a net loss for the quarter of \$34.9 million (\$0.62 per share) compared to a net loss of \$32.1 million (\$0.96 per share) for the same period in 2003.
9	The Company ended the quarter with approximately \$103 million in cash, cash equivalents, securities available-for-sale, and interest receivable.
10	"We continue to be encouraged and enthusiastic about the prolonged survival
11	and relatively low adverse event rates being observed in our XYOTAX pivotal trials in non-small cell lung cancer (NSCLC) and look forward to reporting the preliminary
12	results early next year," stated James A. Bianco, M.D., President and CEO of CTI. "In addition, the Gynecologic Oncology Group (GOG) had a very successful meeting
13	with the FDA and is now in the process of readying clinical sites to initiate a XYOTAX phase III clinical trial in ovarian cancer. This milestone, coupled with the
14	completion of the three STELLAR pivotal trials and our progress in opening clinical sites for our phase III trial of pixantrone in aggressive relapsed non-Hodgkin's
15	lymphoma (NHL) has positioned the Company for a very exciting 2005."
16	81. On December 20, 2004, the Individual Defendants caused or allowed Cell
17	Therapeutics to issue a press release entitled "Cell Therapeutics, Inc. Announces \$18.4 Million
18	Direct Equity Placement." The press release stated in part:
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20	approximately 2,586,000 shares of its common stock to several institutional investors in a registered direct offering at a negotiated price per share of \$7.10.
21	The shares of common stock in this offering are being issued under an
22	existing shelf registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission on March 22, 2004.
23	82. On January 27, 2005, the Individual Defendants caused or allowed Cell Therapeutics
24	to issue a press release entitled "XYOTAXTM Pivotal Trial in Non-Small Cell Lung Cancer,
25	STELLAR 3, Reaches Required Number of Events; STELLAR Trial Updates Presented at the Piper
26	Jaffray Healthcare Conference." The press release stated in part:
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At the Piper Jaffray Healthcare Conference, Cell Therapeutics, Inc. (CTI) announced that it is on track to report results in late March or early April from the XYOTAXTM pivotal trial in non-small cell lung cancer (NSCLC), known as STELLAR 3, now that the required number of events (deaths) for data analysis has been reached. Due to prolonged survival rates in this blinded trial, CTI had to delay the data analysis from the date anticipated when the trial was initiated in November 2002. The company also updated its progress on the two other ongoing pivotal trials in NSCLC, STELLAR 4 and STELLAR 2. In STELLAR 4, approximately 250 of the 313 required events have been reached and in STELLAR 2, 578 out of the 635 required events have been reached. CTI expects results from STELLAR 4 in the second quarter of this year and results from STELLAR 2 in the third quarter.

83. On February 28, 2005, the Individual Defendants caused or allowed Cell Therapeutics to issue a press release entitled "CTI Reports 2004 Quarterly and Year End Results; XYOTAXTM STELLAR 3 Pivotal Trial Results Expected for the First Half of March Provide Potential for 2005 to Be Transforming Year for CTI." The press release stated in part:

Cell Therapeutics, Inc. (CTI) reported financial results for the quarter and year ended December 31, 2004. Total revenues for the quarter were \$8.1 million compared to \$7.2 million in the fourth quarter of 2003. CTI reported a net loss for the quarter of \$43.5 million (\$0.72 per share) compared to net loss of \$36.7 million (\$1.09 per share) for the same period in 2003.

Total revenues for the year ended December 31, 2004, rose to \$29.6 million compared to \$24.8 million in 2003. For the year, CTI posted a net loss of \$252.3 million, including \$87.4 million related to an in-process research and development charge as a result of the acquisition of Novuspharma S.p.A., compared to a net loss of \$130.0 million in 2003. The Company ended the year with cash, cash equivalents, securities available-for-sale and interest receivable of approximately \$116.0 million. Sales of TRISENOX(R) for the quarter were \$6.4 million compared to \$6.6 million in the same period in 2003. The Company had previously guided for lower sales as a result of the launch of a competing product and foresees 2005 net sales of TRISENOX of approximately \$29 million as the commercial team prepares for the potential launch of XYOTAX.

"We made significant progress in 2004 across all aspects of our business and are now hoping to harvest the rewards of those efforts as we prepare to analyze the results of three phase III trials for XYOTAX in lung cancer for the potential submission of a new drug application (NDA) later this year," noted James A Bianco, M.D., President and CEO of CTI. "With everyone focused on XYOTAX, it is easy to forget that we also have the potential for an interim analysis for our pivotal trial of pixantrone in aggressive lymphoma at the end of this year, which could lead to an NDA submission in 2006. With a robust pipeline of novel oncology products and upcoming pivotal milestones, we believe this may be a transforming year for CTI."

THE TRUTH IS DISCLOSED

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84. On March 7, 2005, the Individual Defendants caused or allowed Cell Therapeutics to issue a press release entitled "STELLER 3 Pivotal Trial Shows XYOTAXTM Reduces Side Effects of Paclitaxel With Equivalent Efficacy in the Treatment of Non-Small Cell Lung Cancer (NSCLC) Patients; Study Misses Primary Endpoint, Meets Standard Statistical Test for Non-Inferiority; STELLAR 3 Trial Demonstrates Longest Median Survival Reported in PS2 NSCLC Patients; Tolerability and Convenience Favor XYOTAX." The press release stated in part:

"We are disappointed that XYOTAX in combination with carboplatin showed equal efficacy after the unprecedented blended median and 1-year survival we saw on the trial. We are encouraged by the preliminary analysis, which demonstrates a significant XYOTAX treatment effect, reduction in toxicities, and increased patient convenience," stated James A. Bianco, M.D., President and CEO of CTI. "We look forward to our upcoming discussion with FDA regarding our STELLAR 2 amendment and the preliminary results of STELLAR 3, as well as having results from STELLAR 2 in April, with STELLAR 4 results coming in shortly thereafter."

- 85. On this disastrous news, the Company's shares plummeted 50% in a single day on volume of more than 33 million shares.
- 86. On May 18, 2005, Dr. Langer presented STELLAR 3's complete, "unblinded," results at the 2005 conference of the American Society of Clinical Oncology. During the conference, the disclosure was finally made that the majority of patients enrolled in the study were from Eastern Europe and Russia and were, on average, 10 years younger than the other participants: "The majority of enrollee[s] 63% came from Eastern Europe with roughly half this percentage from Russia, 23% came from the U.S. and 14% came from Western Europe and Canada ... The primary endpoint was not met."
 - 87. Additionally, Dr. Langer stated,

"There was no significant difference in survival between the two arms. Median survivals [of] 7.8 months for the XYOTAX arm, [and] 7.9 months for the Paclitaxel containing arm, [with] identical one-year survival rates at 31% ... However, when we examined the full population, there was a significant difference in survival by geographic region. The median survival for the U.S., Western Europe and Canada was 6.5 months compared to 8.7 months in Eastern Europe. ... A median survival for the XYOTAX arm in the U.S. was 7.2 months versus 5.8 months. ... Median survival for Western Europe and Canada on the XYOTAX arm [was] 6.4 months versus 6.9 months for the Paclitaxel arm... In Eastern Europe, the median

VERIFIED AMENDED SHAREHOLDER DERIVATIVE COMPLAINT -31-

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survival was 8.2 months in the XYOTAX arm compared to 9.4 months in the Paclitaxel containing arm..."

As alleged herein, the Individual Defendants knew or should have known that the longer survival times were not the product of a XYOTAX survivability benefit but rather the result of other problems with the STELLAR 3 study.

- 88. Dr. Langer further stated, "While median survival was 9.4 months in Eastern Europe on the Paclitaxel arm on an intend to treat basis, this number drops to 8.5 months, when we examined patients who were clearly eligible and excluded those who were deemed ineligible based on inaccurate staging; 23 patients overall 20 in the Paclitaxel arm and 3 in the XYOTAX arm. That's 70% are from Eastern Europe...."
- 89. Finally, Dr. Langer admitted that, "[t]he differences in outcome by region may ... have been due to disparities in baseline characteristics. At 58 the median age in Eastern Europe was nearly 10 years younger than the U.S."
- 90. In a follow-up conference call to the 2005 American Society of Clinical Oncology presentation, defendant Bianco, in response to a question from Baltimore analyst Ed Gabrielson regarding the stages of lung cancer found in Eastern European patients, again admitted, "there's about a 15 percentage point difference between the rest of the world and [the] U.S. There were also 20 patients that were probably IIIA rather than IIIB that were enrolled." Finally, Bianco agreed with Ed Gabrielson's comment that "it [] really sound[s] like something [wa]s wrong with the way the trial was run in Eastern Europe."
- 91. In the wake of the STELLAR 3 fiasco and the Company's slide toward financial oblivion resulting from it, four directors, Fluke, Platzer, Spinelli and Link, resigned from Cell Therapeutics' Board. On August 19, 2005, the Company filed a Form 8-K with the SEC that disclosed the following regarding the resignations:

On August 19, 2005, four members of the board of directors of Cell Therapeutics, Inc. (the "Corporation") resigned. John M. Fluke, Jr., Erich Platzer, M.D. and Silvano Spinelli resigned as directors of the Corporation effective immediately. Mr. Fluke served on the Corporation's Audit Committee and Nominating and Governance Committee. In connection with his resignation, Mr. Spinelli provided the Corporation

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written correspondence concerning the circumstances of his resignation, a copy of which is attached hereto as Exhibit 17.1. Max E. Link Ph.D., resigned as Chairman of the board of directors and from the Corporation's Compensation Committee and Audit Committee effective as of September 30, 2005.

The Corporation believes that the departing directors resigned because they believed that the board of directors of the Corporation should replace the current Chief Executive Officer.

The Corporation has provided each of Mr. Fluke, Mr. Spinelli, Dr. Platzer and Dr. Link with a copy of the disclosures herein.

92. On that same date, the remaining directors, who are each named as defendants in this action, caused or allowed the Company to issue a press release entitled, "Four Directors Leave CTI Board Two Staff Promoted to Senior Management Team." In the press release, defendant Nudelman attempted to spin the board resignations as follows:

"The resigning board members felt there was a need for a change in the leadership of the company," said Phillip M. Nudelman, Ph.D., chair of the board's Nominating and Governance Committee. "The other members of the board, however, demonstrated their commitment to the current CEO and the strategic direction the company's management team is pursuing."

- 93. Spinelli in connection with his departure drafted a letter of resignation to the Chairman of the Board. The letter laid out the truth behind the resignations- the four resigning Board members were unable to remove defendants from their positions of control at the Company. Spinelli's letter stated uneqivaocally, "My resignation is due to the denial by the Board of Directors of CTI to replace James Bianco with a more credible and reliable CEO in the interest of shareholders and the company."
- 94. Thus, in clear recognition of defendants' breaches of fiduciary duties, directors Fluke, Platzer, Spinelli and Link attempted to effect a positive change in the Company's leadership by ousting defendants from their entrenched positions of control. Unfortunately, these directors were unable to do so as they did not control a majority of the Board.

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REASONS THE STATEMENTS WERE IMPROPER

- 95. The statements contained herein were materially false and misleading when made because the Individual Defendants caused or allowed the Company to fail to disclose or indicate the following:
- (a) that the observations associated with XYOTAX evidenced that the primary endpoint for the XYOTAX study would not be met, as claimed;
- (b) that claims associated with the Company's ability to commence pre-launch activities or otherwise even begin to submit an NDA for XYOTAX were grossly overstated; in fact, the Company's ability to ever reach these points is highly questionable; and
- (c) that the survival rate for individuals with NSCLC using XYOTAX were not superior to the prevailing treatment.
- 96. As a result of the Individual Defendants' actions, Cell Therapeutics' market capitalization has been damaged by over \$428 million.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

- 97. Plaintiff brings this action derivatively in the right and for the benefit of Cell Therapeutics to redress injuries suffered, and to be suffered, by Cell Therapeutics as a direct result of the breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. Cell Therapeutics is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.
- 98. Plaintiff will adequately and fairly represent the interests of Cell Therapeutics in enforcing and prosecuting its rights.
- 99. Plaintiff is and was an owner of the stock of Cell Therapeutics during times relevant to the Individual Defendants' wrongful course of conduct alleged herein, and remains a shareholder of the Company.

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consisted of the following nine individuals: defendants Bianco, Gregorian, Nudelman, Mundinger,

and Singer and directors Fluke, Platzer, Spinelli and Link. Plaintiff did not made any demand on

the Board of Cell Therapeutics to institute this action because such a demand would have been a

Fluke, Platzer, Spinelli and Link attempted to effect a positive change in the Company's leadership

by ousting defendants from their entrenched positions of control. Unfortunately, these directors

were unable to do so as they did not control a majority of the Board. Defendants Bianco, Gregorian,

Nudelman, Mundinger, and Singer who did control a majority of the Board blocked Fluke's,

Platzer's, Spinelli's and Link's efforts. These defendants were acting to protect of their own interests

at the expense of the Company in a conscious disregard of their fiduciary duties of loyalty, due care

and good faith. Further, the Board acted to protect defendant Bianco who was clearly involved in

the Company's improper disclosures regarding the development of XYOTAX. Accordingly, any

demand on defendants Bianco, Gregorian, Nudelman, Mundinger and Singer would have been futile;

responsibilities relating to compensation of the Company's executive officers, including the CEO,

oversees all compensation programs involving the use of the Company's stock and produces an

annual report on executive compensation in accordance with applicable rules and regulations for

Compensation Committee met seven times in 2003. According to the Company's public website,

inclusion in the Company's proxy statement for its annual meeting of shareholders.

futile, wasteful and useless act, particularly for the following reasons:

The Board of Cell Therapeutics, at the time of the filing of the original complaint,

In clear recognition of defendants' breaches of fiduciary duties, directors

The Compensation Committee of the Board discharges the Board's

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VERIFIED AMENDED SHAREHOLDER **DERIVATIVE COMPLAINT -35-**

Nudelman and Singer is futile;

MULFINGER LAW GROUP PLLC

defendants Gregorian and Mundinger controlled two thirds of the Compensation Committee. As these defendants singularly control the other defendants' awards, the remaining members of the Board will not institute this action against defendants Gregorian and Mundinger. To do so would jeopardize each defendant's personal financial compensation. Thus, demand on defendants Bianco, 13555 Bel-Red Road, Suite 111A

Bellevue, WA 98005

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1	(c) The principal professional occupation of defendant Bianco is his employmen
2	with Cell Therapeutics, pursuant to which he received and continues to receive substantial monetary
3	compensations and other benefits. Specifically, for FY:04 and FY:03, Cell Therapeutics paid
4	defendant Bianco \$1,112,235 and \$3,053,665 in salary, bonus, restricted stock awards and other
5	compensation, and granted him 125,000 options to purchase Cell Therapeutics stock in FY:03
6	Accordingly, defendant Bianco lacked independence from defendants Gregorian and Mundinger
7	defendants who are not disinterested and/or independent and who exert influence over defendan
8	Bianco's compensation by virtue of their positions as two thirds of the Compensation Committee
9	This lack of independence rendered defendant Bianco incapable of impartially considering a demand
10	to commence and vigorously prosecute this action;
11	(d) The principal professional occupation of defendant Singer is his employmen

- (d) The principal professional occupation of defendant Singer is his employment with Cell Therapeutics, pursuant to which he received and continues to receive substantial monetary compensations and other benefits. Specifically, for FY:04 and FY:03, Cell Therapeutics paid defendant Singer \$560,887 and \$1,223,596 in salary, bonus, restricted stock awards and other compensation, and granted him 75,000 options to purchase Cell Therapeutics stock in FY:03. Accordingly, defendant Singer lacked independence from defendants Gregorian and Mundinger, defendants who are not disinterested and/or independent and who exert influence over defendant Singer's compensation by virtue of their positions as two thirds of the Compensation Committee. This lack of independence rendered defendant Singer incapable of impartially considering a demand to commence and vigorously prosecute this action;
- (e) According to the Company's public website, defendants Mundinger and Nudelman comprise two thirds of the Nominating and Governance Committee. The Committee is responsible for: (i) assisting the Board by identifying prospective director nominees and to recommend to the Board the director nominees for each annual meeting of shareholders; (ii) developing and recommending to the Board the governance principles applicable to the Company; (iii) overseeing the evaluation of the Board and management; and (iv) recommending to the Board

director nominees for each committee. Further, the Committee determines the form and amount of director compensation and conducts an annual review of director compensation. The Nominating and Governance Committee met once in 2003 and met four times in 2004. Nonetheless, defendants Mundinger and Nudelman failed to fulfill their duties and responsibilities to oversee the evaluation of the Board and management as evidenced by the conduct discussed herein and as required by the Nominating and Governance Committee Charter. By such actions, defendants Mundinger and Nudelman breached their duties by causing or allowing the conduct discussed herein. As a result of these defendants' breach of their duties, any demand upon them is futile;

- (f) Defendants Mundinger and Nudelman singularly control the rest of the directors' positions and awards by virtue of their position as the two thirds of the Nominating and Governance Committee. Defendants Mundinger and Nudelman are responsible for identifying qualified individuals to become members of the Board, recommending Board nominees for each of the Board's committees, and determining the form and amount of director compensation. Therefore, defendants Bianco, Gregorian, and Singer will not initiate suit against defendants Mundinger, and Nudelman. Thus demand on defendants Bianco, Gregorian, and Singer is futile;
- that, "[o]ne of the duties of the Board of Directors of Cell Therapeutics, Inc. (the "Company") *is to oversee the chief executive officer and other senior management in the competent and ethical operation of the corporation*. The Board of Directors wishes to set standards to ensure that the Company is committed to business success through the maintenance of the highest standards of responsibility and ethics...." The CGG go on to state that, "[t]he fundamental role of the directors is to exercise their business judgment to act in what they reasonably believe to be (sic) the best interests of the Company and its shareholders. In fulfilling that responsibility the directors should be able to rely on the honesty and integrity of the Company's senior management and legal, accounting, financial and other advisors.... The board believes that it is critical that the Company speak with one voice, and that, absent special circumstances, management speak for the Company...." It further

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states that, "[t]he board has complete access to all Company officers and employees." Defendants Bianco, Gregorian, Nudelman, Mundinger and Singer failed to comply with the Corporate Governance Guidelines as evidenced by the conduct discussed herein. By such actions, these defendants breached their duty, as outlined in the CGG, by causing or allowing the conduct discussed herein. As a result of these defendants' breach of their duties, any demand upon them is futile;

(h) The Cell Therapeutics Board has adopted a Code of Ethics for Senior Executive and Financial Officers ("Code") "to promote the honest and ethical conduct of the Senior Officers (as defined below) of Cell Therapeutics, Inc. ("CTI"), including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; full, fair, accurate, timely and understandable disclosure in periodic reports filed by CTI and compliance with all applicable rules and regulations applicable to CTI and its officers." The Code goes on to state that, "[t]his Code of Ethics is applicable to CTI's chief executive officer ... 'Senior Officers.' While we expect honest and ethical conduct in all aspects of our business from all of our employees, we expect the highest possible honest and ethical conduct from our Senior Officers ... CTI's Code of Business Conduct and Ethics, which this Code of Ethics for Senior Executive and Financial Officers supplements, sets forth the fundamental principles and key policies and procedures that govern the conduct of all CTI employees. You are bound by the requirements and standards set forth in the CTI Corporation Code of Business Conduct and Ethics, as well as those set forth in this Code of Ethics and other applicable policies and procedures. Compliance with this Code of Ethics is a condition of your employment and any violations of this Code may result in disciplinary action, up to and *including termination of your employment.*" It further states that, "[y]ou are expected to comply with both the letter and spirit of all applicable laws, rules and regulations governing the conduct of our business and to report any suspected violations of all applicable laws, rules and regulations to the Chair of the Audit Committee." The Code continues by stating that, "[a]s a public company, CTI is required to file periodic and other reports with the Securities and Exchange Commission ("SEC").

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CTI's policy is to make full, fair, accurate, timely and understandable disclosure in compliance with all applicable laws and regulations in all reports and documents that CTI files with, or submits to, the SEC and in all other public communications made by CTI. As a Senior Officer, you are required to promote compliance with this policy and to abide by all CTI standards, policies and procedures designed to promote compliance with this policy." Defendants Bianco failed to comply with the Code of Ethics for Senior Executive and Financial Officers as evidenced by the conduct discussed herein. By such actions, defendant Bianco breached his duties by causing or allowing the conduct discussed herein which is an express violation of the Code. As a result of Bianco's breach of his duties, any demand upon him is futile;

- (i) The Individual Defendants and senior management participated in the wrongs complained of herein. Cell Therapeutics directors are not disinterested or independent due to the following: defendants Bianco, Gregorian, Nudelman, Mundinger and Singer served on the Cell Therapeutics Board during the Relevant Period. Pursuant to their specific duties as Board members, each was charged with the management of the Company and to conduct its business affairs. Each of the above referenced defendants breached the fiduciary duties that they owed to Cell Therapeutics and its shareholders in that they failed to prevent and correct the false and misleading press releases concerning the Company's drug XYOTAX. Thus, the Cell Therapeutics Board cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action because its members are interested personally in the outcome as it is their actions that have subjected Cell Therapeutics to millions of dollars in liability for possible violations of applicable securities laws;
- (j) The Individual Defendants, because of their inter related business, professional and personal relationships, have developed debilitating conflicts of interest that prevent the Board members of the Company from taking the necessary and proper action on behalf of the Company as requested herein. In addition to the conflicts that exist as a result of their participation in the dissemination of the improper statements concerning the development of XYOTAX, as

detailed herein supra, the majority of the Board, including the defendants listed below, are subject to the following prejudicial entanglements:

(i) Nudelman and Singer Are Long Time Business Associates:

Defendant Nudelman is the President, Chief Executive Officer and a director of the Hope Heart Institute, and has been since May 2000. Defendant Singer is a member of the scientific advisory board of the Hope Heart Institute. In November 2002, Cell Therapeutics entered into a Sponsored Research Agreement with The Hope Heart Institute to perform research specified by us and reviewed by a joint research committee comprised of individuals from our company and from The Hope Heart Institute. The Agreement has a term of two years and in addition to monthly payments, the Individual Defendants caused the Company to grant a fully vested warrant to the Hope Heart Institute to purchase 100,000 shares of Cell Therapeutics' common stock at a purchase price of \$10.00 per share. Because of their long standing and entangling business and professional relationships, neither defendant Nudelman nor defendant Singer will take the action requested by plaintiff herein against one another or the remainder of the Individual Defendants.

(ii) Bianco and Singer Are Long Time Business Associates:

Prior to founding Cell Therapeutics, Bianco was an assistant professor of medicine at the University of Washington, Seattle and an assistant member in the clinical research division of the Fred Hutchinson Cancer Research Center. From 1990 to 1992, Bianco was the director of the Bone Marrow Transplant Program at the Veterans Administration Medical Center in Seattle. Singer was a professor of medicine at the University of Washington and a full member of the Fred Hutchinson Cancer Research Center. From 1975 to 1992, Dr. Singer was the chief of medical oncology at the Veterans Administration Medical Center in Seattle. The Fred Hutchinson Cancer Research Center is a corporate affiliate of the Hope Heart Institute. Because of their long standing and entangling business and professional relationships, neither defendant Bianco nor defendant Singer will take the action requested by plaintiff herein against one another or the remainder of the Individual Defendants.

- (k) As of April 19, 2004, defendant Bianco held 255,000 shares of unvested restricted stock. Under section 7.8 of Cell Therapeutics' 2003 Equity Incentive Plan, restricted stock for which restrictions have not lapsed shall revert to the Company. As all unvested restricted shares held by defendant Bianco will never vest unless Bianco retains his positions as President, CEO and director of Cell Therapeutics, any demand upon defendant Bianco is futile;
- (1) As of April 19, 2004, defendant Singer held 90,000 shares of unvested restricted stock. Under section 7.8 of Cell Therapeutics' 2003 Equity Incentive Plan, restricted stock for which restrictions have not lapsed shall revert to the Company. As all unvested restricted shares

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held by defendant Singer will never vest unless Singer retains his positions as Executive Vice President, Chief Medical Officer and director of Cell Therapeutics, any demand upon defendant Singer is futile;

- (m) Each of the key officers and directors knew of and/or directly benefited from the wrongdoing complained of herein;
- (n) The Director Defendants of Cell Therapeutics, as more fully detailed herein, participated in, approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from Cell Therapeutics' stockholders or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties;
- (o) In order to bring this suit, all of the directors of Cell Therapeutics would be forced to sue themselves and persons with whom they have extensive business and personal entanglements, which they will not do, thereby excusing demand;
- (p) The acts complained of constitute violations of the fiduciary duties owed by Cell Therapeutics' officers and directors and these acts are incapable of ratification;
- (q) Each of the Director Defendants of Cell Therapeutics authorized and/or permitted the false statements disseminated directly to the public or made directly to securities analysts and which were made available and distributed to shareholders, authorized and/or permitted the issuance of various of the false and misleading statements and are principal beneficiaries of the wrongdoing alleged herein, and thus could not fairly and fully prosecute such a suit even if such suit was instituted by them;
- (r) Cell Therapeutics has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Cell Therapeutics any part of the damages Cell Therapeutics suffered and will suffer thereby;

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(s) If the Individual Defendants were to bring this derivative action against themselves, they would thereby expose their own misconduct, which underlies allegations against them contained in class action complaints for violations of securities law, which admissions would impair their defense of the class actions and greatly increase the probability of their personal liability in the class actions, in an amount likely to be in excess of any insurance coverage available to the Individual Defendants. In essence, they would be forced to take positions contrary to the defenses they will likely assert in the securities class actions. They will not do this. Thus, demand is futile; and

(t) If the Individual Defendants are protected against personal liability for their acts of mismanagement, abuse of control and breach of fiduciary duty alleged in this Complaint by directors' and officers' liability insurance, they caused the Company to purchase that insurance for their protection with corporate funds, *i.e.*, monies belonging to the stockholders of Cell Therapeutics. However, due to certain changes in the language of directors' and officers' liability insurance policies in the past few years, the directors' and officers' liability insurance policies covering the defendants in this case contain provisions that eliminate coverage for any action brought directly by Cell Therapeutics against these defendants, known as, *inter alia*, the "insured versus insured exclusion." As a result, if these directors were to sue themselves or certain of the officers of Cell Therapeutics, there would be no directors' and officers' insurance protection and thus, this is a further reason why they will not bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage exists and will provide a basis for the Company to effectuate recovery. If there is no directors' and officers' liability insurance at all then the current directors will not cause Cell Therapeutics to sue them, since they will face a large uninsured liability.

101. Moreover, despite the Individual Defendants having knowledge of the claims and causes of action raised by plaintiff, the current Board has failed and refused to seek to recover for Cell Therapeutics for any of the wrongdoing alleged by plaintiff herein.

- 102. Plaintiff has not made any demand on shareholders of Cell Therapeutics to institute this action since such demand would be a futile and useless act for the following reasons:
- (a) Cell Therapeutics is a publicly held company with 66,566,747 shares outstanding, and thousands of shareholders;
- (b) Making demand on such a number of shareholders would be impossible for plaintiff who has no way of finding out the names, addresses or phone numbers of shareholders; and
- (c) Making demand on all shareholders would force plaintiff to incur huge expenses, assuming all shareholders could be individually identified.

COUNT I (Against All Defendants for Breach of Fiduciary Duty)

- 103. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 104. The Individual Defendants owed and owe Cell Therapeutics fiduciary obligations. By reason of their fiduciary relationships, the Officer Defendants and Director Defendants owed and owe Cell Therapeutics the highest obligation of good faith, fair dealing, loyalty and due care.
- 105. The Individual Defendants, and each of them, violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.
- 106. Each of the Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly misrepresent the fact that the additional phase III study requested by the FDA required the Company's drug XYOTAX to demonstrate success a much more difficult primary endpoint and failed to correct the Company's false and misleading press releases and publicly reported guidance. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.
- As a direct and proximate result of the Individual Defendants' failure to perform their 107. fiduciary obligations, Cell Therapeutics has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.
 - 108. Plaintiff on behalf of Cell Therapeutics has no adequate remedy at law.

VERIFIED AMENDED SHAREHOLDER **DERIVATIVE COMPLAINT -43-**

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COUNT II (Against All Defendants for Abuse of Control)

- 108. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 109. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Cell Therapeutics, for which they are legally responsible.
- 110. As a direct and proximate result of the Individual Defendants' abuse of control, Cell Therapeutics has sustained significant damages.
- 111. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.
 - 112. Plaintiff on behalf of Cell Therapeutics has no adequate remedy at law.

COUNT III (Against All Defendants for Gross Mismanagement)

- 113. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 114. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Cell Therapeutics in a manner consistent with the operations of a publicly held corporation.
- 115. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Cell Therapeutics has sustained significant damages in excess of hundreds of millions of dollars.
- 116. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.
 - 117. Plaintiff on behalf of Cell Therapeutics has no adequate remedy at law.

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COUNT IV (Against All Defendants for Waste of Corporate Assets)

- 118. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 119. As a result of the issuance of the false and misleading press releases concerning XYOTAX, and by failing to properly consider the interests of the Company and its public shareholders by failing to conduct proper supervision, defendants have caused Cell Therapeutics to waste valuable corporate assets by paying incentive based bonuses to certain of its executive officers and incur potentially millions of dollars of legal liability and/or legal costs to defend defendants' unlawful actions.
- 120. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.
 - 121. Plaintiff on behalf of Cell Therapeutics has no adequate remedy at law.

COUNT V (Against All Defendants for Unjust Enrichment)

- 122. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.
- 123. By their wrongful acts and omissions, defendants were unjustly enriched at the expense of and to the detriment of Cell Therapeutics.
- 124. Plaintiff, as a shareholder and representative of Cell Therapeutics, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

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PRAYER FOR RELIEF

WHEREFORE, plaintiff demands judgment as follows:

- A. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment;
- B. Directing Cell Therapeutics to take all necessary actions to reform and improve their corporate governance and internal procedures to comply with applicable laws and to protect Cell Therapeutics and its shareholders from a repeat of the damaging events that occurred during the Relevant Period, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the companies' By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote the following Corporate Governance Policies:
- 1. a proposal to strengthen the Boards' supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;
- 2. a provision to permit the shareholders of Cell Therapeutics to nominate at least three candidates for election to the Board; and
 - 3. appropriately test and then strengthen the internal audit and control functions.
- C. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Cell Therapeutics has an effective remedy;
- D. Awarding to Cell Therapeutics restitution from the defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the defendants;
- E. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and
 - F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND 1 2 Plaintiff demands a trial by jury. DATED: December 7, 2005 MULFINGER LAW GROUP PLLC 3 4 By: s/Kirk R. Mulfinger 5 KIRK R. MULFINGER, WSBA #27130 13555 Bel-Red Road, Suite 111A 6 Bellevue, WA 98005 Telephone: 425/283-4155 7 Facsimile: 425/283-4156 8 ROBBINS UMEDA & FINK, LLP BRIAN J. ROBBINS 9 JEFFREY P. FINK 610 West Ash Street, Suite 1800 10 San Diego, CA 92101 Telephone: 619/525-3990 11 Facsimile: 619/525-3991 12 Attorneys for Plaintiff 13 14 15 16 17 18 19 20 21 22 23 24 25 26 G:\Cases\Cell Therapetics\Complaints\Amd Der Cpt\Fernandes Fed Der Amd Cpt final.doc

VERIFIED AMENDED SHAREHOLDER DERIVATIVE COMPLAINT -47-

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